## Structured Protocol Representation SIG Teleconference

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| **Date, Time & Location:** | June 15, 2004; 12:00-1:00 PM EDT; Teleconference |
| **Attendees:** | |

| Center | Attendee |
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| **COH** | Joyce Niland |
| **COH** | Hemant Shah |
| **Mayo Clinic** | Sharon Elcombe |
| **Memorial Sloan-Kettering** | John Speakman |
| **UC Irvine** | Andrea Hwang |
| **University of Pittsburge** | Doug Fridsma |
| **Wake Forest** | Bob Morrell |
| **NCI** | Christo Andonyadis |
| **NCI** | Smita Hastak |
| **BAH** | Chalk Dawson |
| **BAH** | Davis Bu |

**Introduction:**

- Goals and scope
- Identify resources and previous work
- Schedule time for the next face to face meeting

**Goal and Scope:**

- Current environment at Centers:
  - Mayo has spent a fair amount of time trying to characterize protocols in their database
  - Wake forest has organized database according to the protocol life cycle
  - Types of data captured: Raw protocol data; administrative data; patient data
- Importance of Structured Protocol Representations
  - Drives all other downstream activities
  - May assist in development of template forms for standardized data collection by NCI
  - Allows design of form in one place and have metadata used other places
  - Facilitates classification of studies
- Coordination with HL7
  - HL7 Protocols Group: text based model, series of headers with textual information in the headers
  - Not a computable representation, in part because pharmaceutical companies are not as focused in eligibility recruiting, but are more interested in human readable format for reporting
  - HL7 Clinical Decision Support group much more focused on computable methods, e.g. exclusion criteria
  - SIG should focus on computable representation
  - HL7 protocol representation team meeting tomorrow, NCI will present use case for computable format
  - City of Hope has use cases to make protocol representation drive all downstream activities, has models that are HL7 compliant
  - SIG should develop models and CDEs to follow the HL7 RIM
  - May model SIG activities around HL7: develop use cases -> DMIM -> data elements
  - Initial use cases need not be fully fleshed out; may be made

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| | richer during development activities<br>o Would like our use cases to be accepted by HL7, but would proceed with development independent of HL7 timetable<br>• Common datasets and issues raised<br>o Administrative data<br>o Core protocol information<br>o Reporting<br>o Sharing<br>o Computable representation<br>o Data collection<br>• Protocol life cycle<br>o UPMC has focused on protocol life cycle<br>o May help to identify use cases<br>o Life cycle of protocol will define scope of what we want to achieve<br>• Use Cases<br>o Identifying use cases around functionality that does not exist today<br>o Goal for SIG to collect and share existing use cases<br>o Use cases will bound activities and existing tools should be leveraged<br>o Identify strategic goals and timeline; begin goal setting<br>• Standards and Harmonization<br>o Harmonization of use cases and data may be agenda item for future teleconference or face to face meeting<br>o Standard and harmonization for codes may require interface with Vocabulary Working Group<br>o One challenge may be to get centers to talk about same trials in the same way<br>• Separable rules engine may allow flexibility<br>• SIG should strive for computable representation<br>o Flexible and updateable<br>o Maintained over time as environment change<br>o Utilize standard terminologies and data elements<br>• Short term goal: Summary 4 Reporting |
| **Identification of Resources:** | • Goal is to have all systems to have common underlying framework to allow sharing<br>• One challenge is how to uniquely identify protocols<br>• CTEP, FDA, NCI, DCP, SPORES and other external drivers that need to be considered<br>• DCP mirrors well with CTEP system, although there is no current electronic interchange between the systems<br>• Smita Hastak to find out metadata structure CTEP, CTSU<br>• One goal may be to create metamodel to harmonize models across Centers and agencies<br>• Harmonize possible at domain level, but may be difficult at detailed |

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| | level |
| **Future Meetings:** | • Next meeting in two weeks<br>• Additional items to discuss:<br>  ○ Identify use cases<br>  ○ Report on existing resources to use<br>  ○ Interaction with other vendors<br>  ○ Further discussions of plans for face-to-face meetings<br>• June 29, 2004, 12:00-1:00 PM EDT pending confirmation lack of scheduling conflicts |

**Action Items:**

| Name Responsible | Action Item | Date Due | Notes |
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| All Participants | Current and future resource systems, drivers and use cases | Next SIG Teleconference | |
| Smita Hastak | Make available data dictionaries (e.g. CTEP, CTSU) | Next SIG Teleconference | |

**Please list below and attach Meeting Materials and Agenda (if prepared separately):**